

SOUTH CAROLINA DEPARTMENT OF
HEALTH AND ENVIRONMENTAL CONTROL



R.61-47
South Carolina Shellfish

Effective Date:
Includes all amendments through May 26, 2000

**Bureau of Water
2600 Bull Street
Columbia, S.C. 29201**

DISCLAIMER

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NOTICE

In addition to the provisions herein for administrative suspension or revocation of operating permits, the Department may, at its discretion, bring civil court proceedings to enforce provisions of this Regulation, and may also seek to impose criminal sanctions for violation of this Regulation.

Violation of any provision of this Regulation shall be punishable in accordance with Section 44-1-150 and Section 44-1-151, Code of Laws of South Carolina, 1976, and any subsequent amendments.

See Section P. Remedies

TABLE OF CONTENTS
South Carolina Regulation 61-47, Shellfish

| | |
|---|-----------|
| A. GENERAL PROVISIONS | 1 |
| 1. Purpose and Scope | 1 |
| 2. Definitions | 1 |
| B. GROWING AREA SURVEY AND CLASSIFICATION | 8 |
| 1. Sanitary Survey | 8 |
| 2. Classification of Growing Area | 8 |
| 3. Approved Area | 8 |
| 4. Conditionally Approved Area | 9 |
| 5. Restricted Area | 9 |
| 6. Conditionally Restricted Area | 10 |
| 7. Prohibited Area | 11 |
| C. HARVESTING, HANDLING, AND TRANSPORTATION OF SHELLFISH | 13 |
| 1. Harvesting | 13 |
| 2. Handling | 13 |
| 3. Transportation | 16 |
| D. SPECIAL SHELLSTOCK HANDLING | 18 |
| 1. Relaying | 18 |
| 2. Interstate Relaying | 19 |
| 3. Wet Storage | 19 |
| 4. Depletion of Closed Areas | 25 |
| E. SHELLFISH SAMPLING AND STANDARDS | 26 |
| 1. Sampling and Testing | 26 |
| 2. Adulteration Standards | 26 |
| F. LABORATORY PROCEDURES | 27 |
| 1. General | 27 |
| 2. Microbiological | 27 |
| 3. Physical and Chemical | 27 |
| G. CERTIFICATION AND PERMITTING PROCEDURES | 28 |
| 1. General | 28 |
| 2. Issuance of Permits and Certificates | 29 |
| 3. Operations Outside Department Jurisdiction | 29 |
| H. COMPLIANCE AND INSPECTION PROCEDURES | 30 |

| | |
|--|-----------|
| 1. Compliance | 30 |
| 2. Inspections | 31 |
| I. CERTIFIED SHIPPER FACILITIES | 32 |
| 1. General Sanitation and Controls for Certified Shippers | 32 |
| 2. Personnel/Supervision | 34 |
| J. SHUCKER-PACKERS | 36 |
| 1. Shucking Area and Equipment Requirements | 36 |
| 2. Shucking-Packing Operations | 38 |
| 3. Heat Shock Processing of Shellfish for Shucking | 39 |
| K. REPACKERS | 42 |
| L. SHELLSTOCK SHIPPERS | 44 |
| 1. Source | 44 |
| 2. Containers | 44 |
| 3. Records | 44 |
| M. RESHIPPERS | 45 |
| 1. Source | 45 |
| 2. Refrigeration | 45 |
| 3. Records | 45 |
| N. DEPURATION | 46 |
| 1. General Administration | 46 |
| 2. Facility Design and Equipment | 46 |
| 3. Depuration Facility Operations | 47 |
| O. SHELLFISH AQUACULTURE | 49 |
| 1. General | 49 |
| 2. Seed | 50 |
| 3. Open Water Aquaculture | 50 |
| 4. Land Based Shellfish Aquaculture | 51 |
| 5. Aquaculture Permit Applicants Engaging in Polyculture Activities .. | 52 |
| 6. Activities Related to Seed Production | 53 |
| 7. Operators of Shellfish Mariculture Areas | 53 |
| P. REMEDIES | 54 |
| 1. General | 54 |
| 2. Criminal Liability | 54 |

A. GENERAL PROVISIONS

1. Purpose and Scope. This regulation outlines requirements for all producers, processors, and transporters of shellfish and is intended to protect the health of consumers of shellfish. The requirements, standards, and implementation methods outlined herein are consistent with the Interstate Shellfish Sanitation Program (ISSP) Model Code and Guidelines. The Model Code and Guidelines will be used to provide assistance in understanding and implementing this regulation.

2. Definitions. For the purpose of this regulation:

(a) Adulterated means any one of the following:

- (1) Shellfish that have been harvested from closed areas;
- (2) Shellfish that have not been grown, harvested, stored, treated, transported, handled, shucked, packed, or offered for sale in compliance with this Regulation.
- (3) Shellfish deemed unsafe as outlined in E.2;
- (4) Shellfish which are putrid or unfit for human consumption;
- (5) Shellfish which have been exposed to any unsanitary conditions;
- (6) Shellfish which contain any added substance, unless the substance is approved by the Department or the United States Food and Drug Administration;
- (7) Shellfish that do not meet identification and labeling requirements as outlined in C.2 and for depurated shellfish, items N.3(c) and N.3(f).

(b) Adverse Pollution Condition means a state or situation caused by meteorological, hydrological or seasonal events or point source discharges that has historically resulted in elevated fecal coliform levels in a particular harvest area.

(c) Approved Area means State waters that have been approved by the Department for harvesting shellfish for direct marketing or human consumption.

(d) Aquaculture means the cultivation of shellfish in land-based artificial growing or harvest areas, or confined in natural growing or harvest areas as designated by permit from South Carolina Department of Natural Resources. For purposes of this regulation, aquaculture is synonymous with mariculture.

(e) Bulk Shipment means shellstock that are placed in one large volume container for shipment instead of individual or separate containers.

(f) Certified Shipper means a person engaged in the business of selling, distributing or otherwise transporting shellfish and who has a valid certification as a Depuration Processor(DP), Shucker-Packer(SP), Repacker(RP), Shellstock Shipper(SS), or Reshipper(RS) issued by the state in which his facility is located.

(g) Certification Number means the unique identification number assigned by the Department to each Certified Shipper.

(h) Closed Area means a growing area where the harvesting of shellfish is temporarily or permanently not allowed. A closed area status may be placed on any of the four classified area designations -Approved, Conditionally Approved, Restricted, Conditionally Restricted, or Prohibited.

(i) Coliform group means all of the aerobic and facultative anaerobic, gram negative, nonspore forming, rod shaped bacilli which ferment lactose broth with gas formation within 48 hours at 95 Fahrenheit (35 - 0.5 Centigrade).

(j) Commingle or Commingling means the act of combining different lots of shellstock or shucked shellfish.

(k) Conditionally Approved Area means waters that meet approved area criteria under specified environmental conditions and time periods established by the Department. The conditions and time periods are based upon established standards specified in a management plan.

(l) Conditionally Restricted Area means waters that meet Restricted Area criteria under specified environmental conditions and time periods established by the department. The conditions and time periods are based upon established standards for potential pollution sources specified in a management plan. This classification varies from the restricted classification in that it is based on predictable events.

(m) Container means any bag, box, crate, tub, carton, or other conveyance in which shellfish may be held, carried or transported.

(n) Critical Control Point {CCP} means a point, step or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated or reduced to acceptable levels.

(o) Critical deficiency means a condition or practice which results in the production of a product that is unwholesome or presents a threat to the health or safety of the consumer.

(p) Critical limit means the maximum or minimum value to which a physical, biological or chemical parameter must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food safety hazard.

(q) Department means the South Carolina Department of Health and Environmental Control or agents thereof having responsibility for enforcing these regulations.

(r) Depletion means the removal and disposal of all market-size shellfish from a growing area in a manner to prevent human consumption.

(s) Depuration means the process of using a controlled aquatic environment to reduce the level of bacteria and viruses in live shellfish.

(t) Depuration Facility means the physical structure wherein depuration is accomplished, including all the appurtenances necessary to the effective operation thereof.

(u) Depuration Processor (DP) means a person who is certified to receive shellstock from approved or restricted growing areas and submit such shellstock to a depuration process.

(v) Dry Storage means the storage of shellstock out of the water.

(w) Employee means an individual who handles, stores, transports, sells, or distributes shellfish and is employed by someone with a shellfish certificate or permit.

(x) Fecal coliform means that portion of the coliform group which will produce gas from lactose in an EC or A-1 multiple tube procedure liquid medium within 24 (+/- 2) hours in a water bath maintained at 112° Fahrenheit (44.5 +/- 0.2 Centigrade).

(y) Growing Area means an area which supports or could support live shellfish.

(z) HACCP is an acronym that stands for Hazard Analysis Critical Control Point, a systematic, science based approach used in food production as a means to assure food safety.

(aa) HACCP Plan means a written document that delineates the formal procedures that a processor follows to implement the HACCP requirements set forth in 21CFR123.6 as adopted by the Interstate Shellfish Sanitation Conference.

(bb) Harvest means the act of removing shellstock from growing areas and its placement on or in manmade conveyance or other means of transport.

(cc) Harvester means a person who gathers shellfish by any means from a growing area.

(dd) Marina means any water area with a structure (docks, basin, floating docks, etc.) which is: 1) used for docking or otherwise mooring vessels; and, 2) constructed to provide temporary or permanent docking space for more than ten boats, or has more than 200 linear feet of docking space.

(ee) Person means any individual, partnership, company, corporation, trustee, association, agency, or any public or private entity.

(ff) Poisonous or Deleterious Substance means a toxic compound occurring naturally or added to the environment that may be found in shellfish or shellfish growing waters for which a regulatory tolerance limit or action level has been established or may be considered harmful to public health. Examples of naturally occurring substances would include paralytic shellfish toxins and trace elements geologically leached from the environment, such as mercury; examples of added substances would include agricultural pesticides and polynuclear aromatics.

(gg) Process means those actions related to the operation of the Certified Shipper facilities of Depuration Processors(DP), Shucker-Packers(SP), Repackers(RP), Shellstock Shippers(SS), and Reshippers(RS).

(hh) Prohibited Area means waters that have been classified by the Department as prohibited for the harvesting of shellfish for any purpose related to human consumption. A Prohibited Area is a Closed Area.

(ii) Relaying means the transfer of shellstock from Restricted Areas or conditionally Restricted Areas to Approved or Conditionally Approved Areas for natural biological cleansing using the ambient environment as a treatment system.

(jj) Repacker (RP) means a certified shipper who packs shucked shellfish into containers other than those in which they were originally packaged. A Repacker may act as a Shellstock Shipper.

(kk) Repacking means the transfer of shucked shellfish into containers other than those in which they were originally packaged.

(ll) Reshipper (RS) means Certified Shippers who purchase shellfish from other Certified Shippers and sell or distribute the shellfish without repackaging.

(mm) Restricted Area means waters that have been classified by the Department as Restricted and where harvesting for direct marketing is not allowed. Shellfish may be harvested from restricted areas only by special permit.

(nn) Sanitary Survey Report means a written evaluation of all actual and potential pollution sources and environmental factors which affect shellfish growing area water quality.

(oo) Sanitize means adequate treatment of food contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance and in substantially reducing the number of other microorganisms. Such treatment shall be safe and not adversely affect shellfish.

(pp) Scheduled Depuration Process means the process which places shellfish harvested from Conditionally Restricted, Restricted, or Approved waters into a controlled aquatic environment selected by the processor and that is approved by the Department as adequate to effectively reduce the level of bacteria and viruses in live shellfish.

(qq) Seed means young shellstock used for propagating new shellstock.

(rr) Shellfish means all edible species of oysters, clams, mussels, and scallops; either shucked or in the shell; fresh or fresh frozen; whole or in part, except that scallops shall be excluded when the final product is the adductor muscle only.

(ss) Shellstock means shellfish in the shell after harvesting.

(tt) Shellstock Shipper (SS) means a Certified shipper who grows, harvests, buys, or sells shellstock. A Shellstock Shipper is not certified to shuck shellfish or repack shucked shellfish. A Shellstock Shipper may repack shellstock or act as a Reshipper.

(uu) Shucked Shellfish means shellfish which have been removed from their shells.

(vv) Shucker-Packer (SP) means a Certified Shipper who shucks and packs shellfish. A Shucker-Packer may act as a Repacker, Shellstock Shipper, or a Reshipper.

(ww) Systematic Random Sampling is a field sampling and data analysis design that employs a preestablished sampling schedule and assumes that a

statistically representative cross section of all meteorological, hydrographic, and/or other pollution events will be included in the data set.

(xx) Vehicle means any truck, car, bus, railcar, aircraft, boat, ship, or other means by which shellfish is transported from one location to another.

(yy) Wet Storage means storage of marketable shellfish in water after initial harvest.

B. GROWING AREA SURVEY AND CLASSIFICATION

1. Sanitary Survey. A sanitary survey of shellfish growing areas shall be conducted by the Department, and each area will be classified prior to its approval for shellfish harvesting. Sanitary Surveys and reports will be conducted and prepared consistent with ISSP Guidelines.

2. Classification of Growing Area. Shellfish growing areas shall be identified and assigned harvesting classifications of “approved”, “conditionally approved”, “restricted”, “conditionally restricted”, or “prohibited.” The assigned classification will be based upon a sanitary survey conducted by the Department. Growing areas for which a sanitary survey has not been completed shall be classified as “prohibited.” The Department may also designate an area as a closed area and prohibit harvesting when it determines that conditions have occurred that may potentially render shellfish unsafe for human consumption.

3. Approved Area. Growing areas shall be classified “approved” when the sanitary survey concludes that fecal material, pathogenic microorganisms, and poisonous or deleterious substances are not present in concentrations which would render shellfish unsafe for human consumption. “Approved” area classification shall be determined upon a sanitary survey which includes water samples collected from stations in the designated area adjacent to actual or potential sources of pollution. For waters sampled under adverse pollution conditions, the median fecal coliform Most Probable Number (MPN) or the geometric mean MPN shall not exceed fourteen per one hundred milliliters, and not more than ten percent of the samples shall exceed a fecal coliform MPN of forty-three per one hundred milliliters (per five tube decimal dilution). For waters sampled under a systematic random sampling plan, the geometric mean fecal coliform Most Probable Number (MPN) shall not exceed fourteen per one hundred milliliters, and the estimated ninetieth percentile shall not exceed an MPN of forty three (per five tube decimal dilution). Computation of the estimated ninetieth percentile shall be obtained using ISSP Guidelines.

4. Conditionally Approved Area.

(a) Growing areas may be classified “conditionally approved” when they are subject to temporary conditions of actual or potential pollution. When such events are predictable as in the malfunction of wastewater treatment facilities, non-point source pollution from rainfall runoff, discharge of a major river, potential discharges from dock or harbor facilities that may affect water quality, a management plan describing conditions under which harvesting will be allowed shall be adopted by the Department, prior to classifying an area as “conditionally approved.” Where appropriate, the management plan for each “conditionally approved” area shall include performance standards for sources of controllable pollution, e.g., wastewater treatment and collection systems, evaluation of each source of pollution, and means of rapidly closing and subsequent reopening areas to shellfish harvesting. Memorandums of agreements shall be a part of these management plans where appropriate.

(b) Shellfish shall not be directly marketed from a “conditionally approved” area until conditions for an “approved” classification have been met for a time that should insure the shellfish are safe for consumption.

(c) Shellstock from “conditionally approved” areas which have been subjected to temporary conditions of actual or potential pollution may be relayed to “approved” areas for purification or depurated through controlled purification operations only by special permit issued by the Department.

5. Restricted Area

(a) Growing areas shall be classified “restricted” when sanitary survey data show a limited degree of pollution or the presence of deleterious or poisonous substances to a degree which may cause the water quality to fluctuate unpredictably or at such a frequency that a “conditionally approved” area classification is not feasible. Shellfish may be harvested from areas classified as “restricted” only for the purposes of relaying or depuration and only by special permit issued by the Department and under Department supervision.

(b) The suitability of Restricted Areas for harvesting of shellstock for Relay or Depuration purposes may be determined through the use of comparison studies of background tissue samples with post-process tissue samples, as well as other process verification techniques deemed appropriate by the Department.

(c) For restricted areas to be utilized as a source of shellstock for depuration, or as source water for depuration, the fecal coliform geometric mean MPN of restricted waters sampled under adverse pollution conditions shall not exceed eighty-eight per one hundred milliliters and not more than ten percent of the samples shall exceed a MPN of two hundred and sixty per one hundred milliliters for a five tube decimal dilution test. For waters sampled under a systematic random sampling plan, the fecal coliform geometric mean MPN shall not exceed eighty-eight per one hundred milliliters and the estimated ninetieth percentile shall not exceed an MPN of two hundred and sixty (five tube decimal dilution). Computation of the estimated ninetieth percentile shall be obtained using the formula outlined in B.3.

6. Conditionally Restricted Area.

(a) Growing areas may be classified “conditionally restricted” when they are subject to temporary conditions of actual or potential pollution. When such events are predictable, as in the malfunction of wastewater treatment facilities, non-point source pollution from rainfall runoff, discharge of a major river or potential discharges from dock or harbor facilities that may affect water quality, a management plan describing conditions under which harvesting will be allowed shall be prepared by the Department prior to classifying an area as “conditionally restricted.” Where appropriate, the management plan for each “conditionally restricted” area shall include performance standards for sources of controllable pollution, e.g., wastewater treatment and collection systems and an evaluation of each source of pollution, and description of the means of rapidly closing and subsequent reopening areas to shellfish harvesting.

Memorandums of agreements shall be a part of these management plans where appropriate.

(b) Shellfish may be harvested from areas classified as “conditionally restricted” only for the purposes of relaying or depuration and only by permit issued by the Department and under Department supervision.

(c) For Conditionally Restricted areas to be utilized as a source of shellstock for depuration, the fecal coliform geometric mean MPN of Conditionally Restricted waters sampled under adverse pollution conditions shall not exceed eighty-eight per one hundred milliliters and not more than ten percent of the samples shall exceed a MPN of two hundred and sixty per one hundred milliliters for a five tube decimal dilution test. For waters sampled under a systematic random sampling plan, the fecal coliform geometric mean MPN shall not exceed eighty-eight per one hundred milliliters and the estimated ninetieth percentile shall not exceed an MPN of two hundred and sixty (five tube decimal dilution). Computation of the estimated ninetieth percentile shall be obtained using ISSP guidelines.

7. Prohibited Area.

(a) Growing areas shall be classified “prohibited” if there is no current sanitary survey or if the sanitary survey or monitoring data show unsafe levels of fecal material, pathogenic microorganisms, or poisonous or deleterious substances in the growing area or indicate that such substances could potentially reach quantities which could render shellfish unfit or unsafe for human consumption.

(b) Harvesting of shellfish from Prohibited areas for human consumption shall not be allowed by the Department.

(c) Shellfish may be depleted for non-food use from “prohibited” areas upon approval of the Department and under specified conditions as outlined in D.4.

(d) Growing waters adjacent to sewage treatment plant outfalls and other waste discharges shall be classified as “prohibited.” The following assumptions

and criteria will be considered in determining the area which could be potentially impacted:

- (1) Pollution Conditions;
 - (a) Flow rate;
 - (b) Sewage treatment plant performance;
 - (c) Location of shellfish resources.
- (2) Dispersion, dilution, and time of travel;
 - (a) Current velocity and net transport velocity;
 - (b) Volume;
 - (c) Depth of water;
 - (d) Direction of travel and stratification;
 - (e) Location of discharge;
 - (f) Tidal characteristics;
 - (g) Receiving area geometry.
- (3) Decay rate (bacteriological die-off);
- (4) Bacteriological quality required;
- (5) Adjacent harvest use classification;
- (6) Identifiable landmarks for boundaries.

(e) Growing waters within marinas shall be classified as “prohibited”. Classification of waters adjacent to marinas will be determined using a dilution analysis which incorporates the following assumptions:

- (1) occupancy rate of the marina;
- (2) An assumed rate of boats which will discharge untreated waste;
- (3) An occupancy rate of two (2) persons per boat;
- (4) A rate of discharge of 2×10^9 fecal coliform per person per day;
- (5) Wastes are completely mixed in and around the marina;
- (6) The volume of water in the vicinity of the marina;
- (7) A theoretical calculated fecal coliform level of 14 MPN per 100

milliliters.

C. HARVESTING, HANDLING, AND TRANSPORTATION OF SHELLFISH.**1. Harvesting.**

(a) Harvesting of Shellfish from Closed Waters -It shall be unlawful to harvest, remove, take, buy, sell, offer for sale, or possess shellfish from areas closed by the Department. This Section shall not be construed to prevent harvesting as permitted by the Department.

(b) Harvesting Vehicles -Vehicles used for harvesting and storing shellstock shall be constructed, operated, and maintained to prevent contamination and co-mingling of shellfish from different harvest areas. Decks and storage bins shall be constructed and located in a manner which will prevent bilge water, overboard polluted water, and any other contaminants from contacting the shellfish.

(c) Temperature Maintenance -Within twenty hours after harvest, shellstock temperature shall be maintained between thirty-four and forty-five degrees fahrenheit (one and seven degrees centigrade). This temperature shall be maintained during all handling, storage and transportation of shellstock.

(d) Disposal of Body Waste -Untreated human fecal waste shall not be discharged by harvesters into an area approved for shellfish harvesting.

2. Handling.

(a) Shellstock Identification -Shellstock offered for sale or in the possession of any person in a quantity exceeding the recreational limit established by the South Carolina Department of Natural Resources (SCDNR) shall be tagged as follows.

(1) Tags shall be securely fastened to the outside of each container in which shellstock is transported. Bulk shipments in one container and from the same source may have one tag with all required information attached.

(2) Tags shall be identified as sale or harvest tags. They shall be durable for at least ninety (90) days, waterproof, and a minimum of two and five-eighths inches by five and one-fourth inches in size.

(a) Sale Tags - Shellstock offered for sale shall be tagged with a sale tag. Sale tags shall be attached to each container of shellstock prior to sale or distribution. The information on the tag shall be accurate, legible, complete, and arranged in the specific order as follows:

(i) The name, address and State Shellfish Control Agency (SSCA) certification number assigned to the Certified Shipper possessing the shellfish:

(ii) The SSCA assigned Certified Shipper certification number of the original processor, including the state abbreviation;

(iii) The date of harvesting;

(iv) The most precise description of the harvest location as is practicable (e.g., Long Bay, Smith Bay or an identifying number) that can be easily located by maps or charts. This description shall include the initials of the state in which the shellfish were harvested;

(v) Type and quantity of shellfish;

(vi) The following statement will appear in bold, capitalized type:

“THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS.”

(vii) When the shellstock has been placed in wet storage, the statement: **“THESE SHELLFISH ARE A PRODUCT OF (ORIGINAL PRODUCING STATE) AND WERE WET STORED AT (SOUTH CAROLINA CERTIFICATION NUMBER) FROM (DATE) TO (DATE)”** shall be included on the tag.

(viii) Sale tags shall contain the following (or substantially equivalent) consumer advisory message: **“RETAILERS, INFORM YOUR CUSTOMERS - CONSUMING RAW OR UNDERCOOKED MEATS, POULTRY, SEAFOOD, SHELLFISH OR EGGS MAY INCREASE YOUR RISK OF FOOD BORNE ILLNESS, ESPECIALLY IF YOU HAVE CERTAIN MEDICAL CONDITIONS.”**

(b) Harvest Tags - Shellstock awaiting delivery to a Certified Shipper shall be tagged with a harvest tag. The information on this tag shall be legible and include the following information:

- (i) Harvester's Name;
- (ii) Harvester's State Shellfish Ground Permit number, if applicable;
- (iii) Date and time harvested;
- (iv) Harvest area;
- (v) Name and certificate number of the certified shipper to which the shellfish are to be delivered.

(3) Tag information shall not be altered in any way.

(4) Shellstock harvested from State Waters shall be delivered only to the Certified Shipper specified on the harvest tag utilized during harvest.

(5) Shellstock harvested from State waters and placed in storage at the facilities of a Certified Shipper shall remain tagged with a harvest tag prior to sale, distribution, or re-tagging with a sale tag.

(b) Shucked Shellfish Labeling and Identification - Packages of shucked shellfish or frozen shucked shellfish meat shall be labeled as follows:

(1) All packages of shucked shellfish or frozen shucked shellfish shall be labeled to comply with the requirements of the Federal Fair Packaging and Labeling Act as adopted under Section 39-25-120 of the South Carolina Food and Cosmetic Act:

(2) All packages of shucked shellfish or frozen shucked shellfish shall be labeled to comply with the requirements of Section 39-25-160 of the South Carolina Food and Cosmetic Act;

(3) The principal display panel of all packages of shucked shellfish or frozen shucked shellfish shall contain the certification number of the shucker-packer or repacker;

(4) All packages of shucked shellfish or frozen shucked shellfish shall be dated in the following manner;

(i) The lid, and side wall or bottom, of all packages of shucked or frozen shucked shellfish with a net weight of sixty-four fluid ounces or more shall legibly display the word "SHUCKED" followed by the actual date of shucking;

(ii) The principal display panel of all packages of shucked or frozen shucked shellfish with a net weight of less than sixty-four fluid ounces shall legibly display the words "SELL BY" followed by the shucker-packer's recommended last date of sale;

(iii) The date shall consist of the common abbreviation for the month of the year and the day of the month, or the numerical day of the year (Julian calendar day). For frozen shucked shellfish, the year will be added to the date.

(5) Frozen shucked shellfish shall be labeled as frozen in type of equal prominence immediately adjacent to the name of the shellfish.

(c) Ice - When used in shellfish handling activities, ice shall be sanitary and from a source approved by the Department.

(d) Temperature Maintenance - Within twenty hours after harvest, shellfish shall be placed under temperature control and be maintained between thirty-four and forty-five degrees Fahrenheit (one and seven degrees centigrade). This temperature shall be maintained during all handling of shellstock or shucked shellfish.

3. Transportation of Shellfish - Vehicles used for transporting shellfish shall be constructed, operated, and maintained to prevent contamination of shellfish. Shellfish transported in unenclosed vehicles shall be covered by tarpaulins or similar covers.

(a) Within twenty hours after harvest, shellfish shall be placed under temperature control and be maintained between thirty-four and forty-five degrees Fahrenheit (one and seven degrees centigrade). This temperature shall be maintained during the transportation of shellstock or unfrozen shucked shellfish.

(b) Frozen shucked shellfish in transportation shall be maintained at or below zero degrees fahrenheit (minus 18 degrees centigrade) at all times.

(c) Dogs, cats, birds, other animals, or unauthorized persons shall not be allowed in any area of a vehicle used for harvesting, holding, storage, or transportation of shellstock except that patrol dogs accompanying security or police officers are permitted.

(d) When ice is used during the transportation of shellfish, it shall be sanitary and from a source approved by the Department.

(e) Each shellfish shipment originating from a Certified Shipper shall be accompanied by a shipping document that includes the following information:

- (1) The name, address, and certification number of the shipping dealer;
- (2) The name and address of the major consignee;
- (3) The kind and quantity of the shellfish product.

D. SPECIAL SHELLSTOCK HANDLING.**1. Relaying.**

(a) Shellstock may be harvested and relayed from Restricted or Conditionally Restricted Areas to Approved or Conditionally Approved Areas for natural biological purification. The shellstock for relaying shall be of such quality that purification will be effective in reducing contaminants to safe levels.

(b) Following approval by the South Carolina Department of Natural Resources, relaying operations may be permitted and supervised by the Department. Only shellfish harvested from waters meeting Approved Area criteria as defined in B.3 shall be certified for marketing.

(c) Applications for Relay Permits must designate whether the shellfish are being relayed for direct marketing or for seed (replanting) purposes.

(d) Shellfish relayed from a Restricted or Conditionally Restricted Area to an Approved Area for subsequent harvesting direct marketing purposes shall remain planted for a period of not less than fourteen consecutive days when the water temperature is above fifty degrees fahrenheit (ten degrees centigrade). If the water temperature is less than fifty degrees fahrenheit (ten degrees centigrade), the Department shall make a determination as to an adequate time period to insure natural purification. Shellfish relayed from a Restricted Area to a Conditionally Approved Area for direct marketing purposes shall remain planted for a period of not less than fourteen consecutive days when the water temperature is above fifty degrees fahrenheit (ten degrees centigrade) and the area is in an open status. If the water temperature is less than fifty degrees fahrenheit (ten degrees centigrade), or if the area is downgraded to a closed status, the Department shall make a determination as to an adequate time period to insure natural purification.

(e) Shellfish relayed for seed (replanting) purposes shall remain planted for a minimum of four months.

(f) Shellfish relayed to Approved or Conditionally Approved areas from Restricted or Conditionally Restricted areas shall not be taken from the Approved or Conditionally Approved areas until approval is granted by the Department.

(g) Areas to which shellstock are relayed shall be readily identified and marked. These areas shall be situated in a manner to avoid contamination of shellstock in adjacent growing areas.

2. Interstate Relaying. Shellstock shall not be relayed from the State to another state without prior approval of the Department and the responsible state agency which will receive the shellstock. The United States Department of Health and Human Services, Food and Drug Administration, shall be informed of such interstate activities.

3. Wet Storage - Harvested shellstock may be held in wet storage in approved shellfish growing waters or land-based ponds or tanks where effective control measures are enforced to keep shellfish fresh and protected from contamination. Proper shellstock identification as outlined in C.2 must be maintained during wet storage.

(a) Permit Requirements - Prior to the Wet Storage of molluscan shellfish in approved near-shore growing waters, application for a Wet Storage facility operating permit shall be made to and obtained from the Department. Prior to the construction, expansion or modification of any land-based Wet Storage facility, application for a Wet Storage Facility Construction Permit shall be made to, and a Wet Storage Facility Construction Permit obtained from, the Department. Prior to operating any land-based Wet Storage facility, application for a Wet Storage Operating Permit shall be made to, and a Wet Storage Operating Permit obtained from, the Department. Wet Storage Operating Permits shall be issued only in conjunction with a Certified Shipper Certificate.

(b) Wet Storage in Approved near-shore shellfish growing waters - Operating Permit Requirements. On an application form provided by the Department, general information related to the proposed construction and

operation of a near-shore wet storage facility shall be submitted for Department review and approval. This information shall be provided in the form of a written operational plan detailing the scope and extent of the proposed activity, including, but not necessarily limited to location, type of construction, and species of shellfish stored. The operational plan shall address the following:

(1) the purpose of the wet storage activity, such as holding, conditioning, or increasing the salt content of shellstock.

(2) any species specific physiological factors that may affect design criteria

(3) location of near-shore storage structures

(4) details of the design and proposed construction of the storage structures which address the following minimum construction standards to:

(i) allow the free flow of water to shellfish; and

(ii) be constructed of non-toxic materials; and

(iii) be constructed so as to protect shellfish from physical, chemical or thermal conditions which may compromise shellfish survival, quality or biological activity.

(iv) comply with section D.3(b)(2).

(c) The Department will issue an operating permit after approval of the operational plan and completion of a successful Department inspection of the constructed facility.

(d) Wet Storage in land-based ponds or tanks

(1) Construction Permit Requirements. An Operational Plan shall be provided in conjunction with the Wet Storage Facility Construction Permit application. The Operational Plan shall address the following:

(a) the purpose of the wet storage activity, such as holding, conditioning or increasing the salt content of shellstock;

(b) any species specific physiological factors that may affect design criteria;

(c) details of the design and proposed construction of the onshore storage facility as required by Section D.3(d)(2), source, quantity and quality of water to be used for wet storage as required by Section D.3(d)(3), and details of the design and proposed construction of any water treatment system.

(2) Construction Requirements- Each land-based wet storage operation shall meet the following design, construction, and operating requirements:

(a) Effective barriers shall be provided to prevent entry of birds, animals, and vermin into the area.

(b) Storage tanks and related plumbing shall be fabricated of non toxic material and shall be easily cleanable.

(c) Tanks shall be constructed so as to be easily accessible for cleaning and inspection, self-draining and fabricated from nontoxic, corrosion resistant materials.

(d) Plumbing shall be designed and installed so that it can be cleaned and sanitized on a regular schedule, as specified in the operating procedures.

(e) Storage tank design, dimensions, and construction shall be such that adequate clearance between shellstock and the tank bottom can be maintained.

(f) Shellstock containers, if used, shall be designed and constructed so that the containers allow the free flow of water to all shellstock within a container.

(g) Buildings -When a building is used for the wet storage operation:

(i) Floors, walls, and ceilings shall be constructed in compliance with the applicable provisions of Chapter I;

(ii) Lighting, plumbing, water and sewage disposal systems shall be installed in compliance with applicable provisions of Chapter I.

(h) Outdoor Tank Operation -When the wet storage operation is outdoors or in a structure other than a building, tank covers shall be used. Tank covers shall:

(i) Be constructed of a light colored material;

(ii) Prevent entry of birds, animals or vermin;

(iii) Remain closed while the system is in operation except for periods of tank loading and unloading, or cleaning.

(3) Water Supply.

(a) The quality of source water prior to treatment shall meet, at a minimum, the bacteriological standards for the restricted classification.

(b) Any well used as source water for wet storage shall be constructed, operated and maintained in accordance with all applicable Departmental regulations .

(c) Except when the source of the water is a growing area in the approved classification, a water supply sampling schedule shall be included in the dealer's operating procedures and water shall be tested according to the schedule.

(d) Results of water samples and other tests to determine the suitability of the water supply shall be maintained for at least 2 years.

(e) Disinfection or other water treatment such as the addition of salt cannot leave residues unless they are Generally Recognized as Safe (GRAS and unless they do not interfere with the shellstock's survival, quality or activity during wet storage.

(f) Disinfected water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multi-tube MPN test per 100 ml. for potable water.

(g) When the laboratory analysis of a single sample of disinfected water entering the wet storage tanks shows any positive result for the coliform group, daily sampling shall be immediately instituted until the problem is identified and eliminated.

(h) When the problem that is causing disinfected water to show a positive result for the coliform group is eliminated, the effectiveness of the correction shall be shown on the first operating day following correction through the

immediate collection, within a 24 hour period, of a set of three samples of disinfected water and one sample of the source water prior to disinfection.

(i) For water that is disinfected by ultra-violet treatment, turbidity shall not exceed 20 nephelometric turbidity units (NTUs) measured in accordance with Standard Methods for the Examination of Water and Wastewater, APHA.

(ii) The disinfection unit(s) for the water supply shall be cleaned and serviced as frequently as necessary to assure effective water treatment.

(i) Continuous Flow-through Systems.

(i) If the system is of continuous flow-through design, water from a growing area classified as:

(a) Approved may be used, without disinfection, in wet storage tanks provided that the near-shore water source used for supplying the system meets the approved classification bacteriological criteria at all times that shellstock are being held in wet storage; or

(b) Other than approved may be used if the source water is continuously subjected to disinfection and it is sampled daily following disinfection.

(ii) When a source classified as other than approved is used, a study shall be required to demonstrate that the disinfection system will consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall:

(a) Include five sets of three samples from each disinfection unit collected for five consecutive days at the outlet from the disinfection unit or at the inlet to at least one of the wet storage tanks served by the disinfection system;

(b) Include one sample daily for five consecutive days from the source water prior to disinfection;

(c) Use NSSP recognized methods to analyze the samples to determine coliform levels;

(d) Require all samples of disinfected water to be negative for the coliform group;

(e) Be repeated if any sample of disinfected water during the study is positive for the coliform group.

(iii) Once sanctioned for use, the water system shall be sampled daily to demonstrate that the disinfected water is negative for the coliform group.

(j) Recirculating Water System.

(i) A study shall be required to demonstrate that the disinfection system for the recirculating system will consistently produce water that tests negative for the coliform group under all operating conditions. The study shall meet the requirements in Section D.3(d)(3)(i)(ii) above.

(ii) Once sanctioned for use, the recirculating water system shall be sampled weekly to demonstrate that the disinfected water is negative for the coliform group.

(iii) When make-up water of more than 10 percent of the water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected within a 24 hour period to reaffirm the ability of the system to produce water free from the coliform group.

(iv) When ultra-violet treatment is used as the water disinfectant, each time new ultraviolet bulbs are installed, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected within a 24 hour period to reaffirm the ability of the system to produce water free from the coliform group.

(k) Operating permit requirements - Following issuance of a facility specific construction permit which includes an approved operational plan and upon completion of construction of the proposed facility application for a wet storage operating permit shall be made on a form provided by the Department.

(l) The Department will issue an operational permit after approval of the application and the completion of a successful Departmental inspection of the constructed facility.

4. Depletion of Closed Areas. If depletion of shellfish in a Prohibited Area is more economical than patrolling, all shellfish of market size and as many of smaller size as can be gathered by reasonable methods may be removed from the area by the Department or under direct supervision of the Department.

E. SHELLFISH SAMPLING AND STANDARDS.

1. Sampling and Testing. Samples of shellfish may be taken at any reasonable time or place and examined bacteriologically or for any other public health reason by agents of the Department. Samples of shellfish shall be furnished as necessary by processors and operators of facilities, trucks, carriers, stores, restaurants, and other places where shellfish are sold. Receipt for shellfish used for sampling shall be given upon request. The type of test to be performed will be included on the receipt.

2. Adulteration Standards. In determining bacteriological adulteration of shellfish, the Department will use an *Escherichia coli* Most Probable Number (MPN) of two hundred and thirty per one hundred grams of sample and a total bacteria count of five hundred thousand per gram. Shellfish containing levels of pathogenic organisms or other substances which render the shellfish potentially unsafe for human consumption shall also be deemed adulterated by the Department.

F. LABORATORY PROCEDURES.

1. General. Laboratory analyses shall be performed by a State laboratory or a laboratory approved by the Department.

2. Microbiological - Microbiological analyses of seawater or shellfish for microorganisms shall be in accordance with American Public Health Association Laboratory Procedures, the Food and Drug Administration Bacteriological Analytical Manual, or by other methods accepted by the Department.

3. Physical and Chemical. Physical and chemical analyses of seawater or shellfish for determinations such as salinity, radionuclides, heavy metals, or poisonous or deleterious substances shall be in accordance with American Public Health Association Laboratory Procedures, the Official Methods of Analysis of the Association of Analytical Chemists, or by other accepted methods.

G. CERTIFICATION AND PERMITTING PROCEDURES.**1. General.**

(a) It shall be unlawful to offer for sale shellfish that have not been processed by a Certified Shipper (see definition).

(b) It shall be unlawful for any person to relay, distribute in interstate commerce, distribute to a Certified Shipper, harvest for depuration, deplete, wet store, conduct aquaculture activities, or process shellfish who does not possess the appropriate valid permit or certificate issued by the Department. The permit or certificate shall be one of the following types:

- (1) Relaying Permit;
- (2) Wet Storage Facility Operating Permit;
- (3) Wet Storage Facility Construction Permit;
- (4) Depletion of Closed Area Permit;
- (5) Depuration Harvest Permit;
- (6) Depuration Facility Construction Permit
- (7) Aquaculture Facility Construction Permit;
- (8) Aquaculture Facility Operating Permit
- (9) Certified Shipper Certificate - One Certified Shipper certification

will be issued to the following type facilities for each location.

- (a) Shucker-Packer;
- (b) Repacker;
- (c) Shellstock Shipper;
- (d) Reshipper;
- (e) Depuration Processor.

(c) Permits and certificates shall be non-transferable.

(d) Permits and certificates issued by the Department shall at all times be posted in a conspicuous place on the premises where such business is conducted. All permits and certificates, unless otherwise specified, shall expire on June 30 of each year.

(e) Only persons who comply with the requirements of this Regulation shall be entitled to receive and retain a permit or certificate.

(f) Nothing in this regulation shall be construed to prevent possession and sale of shellfish by establishments permitted or evaluated under provisions of R.61-25, provided that such shellfish have been processed and labeled in compliance with this regulation.

(g) Nothing in this regulation shall be construed to prevent the intrastate distribution or sale of non adulterated shellfish products by persons not permitted or certified by the Department, provided, however, that these persons may not distribute or sell shellfish products to Certified Shippers.

2. Issuance of Permits and Certificates:

(a) An application shall be made on a form provided by the Department.

(b) Upon receipt of a completed application form, the Department shall make comprehensive onsite inspections of the shellfish operation as may be necessary to determine compliance with the applicable provisions of this Regulation. This inspection shall be conducted within the 120 day period immediately prior to the issuance or renewal of the certification.

(c) Prior to application approval, persons requesting certification as Certified Shippers shall conduct a facility and product specific hazard analysis. The applicant must also have a HACCP plan in addition to a program of sanitation monitoring, verification and record keeping that complies with the Code of Federal Regulations, Title 21, Part 110 (21CFR110) and Part 123 (21CFR123), revised as of April 1, 1997.

(d) A permit or certificate may be suspended or revoked as stated in Items H.1(b) and H.1(d).

3. Operations Outside Department Jurisdiction -Shellfish from operations located outside the jurisdiction of the State may be further processed, sold, or distributed within the State, if such shellfish conform to the provisions of this Regulation or substantially equivalent provisions.

H. COMPLIANCE AND INSPECTION PROCEDURES.**1. Compliance.****(a) Stop Sale or Disposal of Shellfish.**

(1) If it has been determined by the Department that shellfish have not been grown, harvested, stored, treated, transported, handled, shucked, packed, or offered for sale in compliance with this Regulation, those shellfish shall be deemed adulterated.

(2) Shellfish or shellfish products determined to be adulterated shall be subject to stop sale or disposal by the Department. The Department may temporarily or permanently issue an order to stop sale, condemn, destroy, recall, or otherwise dispose of all shellfish or shellfish containers found to be adulterated.

(3) Adulterated shellfish shall be disposed of at the discretion of the Department.

(b) Suspension of Permits or Certifications - If the Department has evidence that an operator of a shellfish activity or facility has created or is responsible for conditions that may cause shellfish to become adulterated, the permit or certificate may be suspended or revoked upon notice to the permit or certificate holder.

(c) Reinstatement of Suspended Permits or Certifications -A person whose permit or certification has been suspended may at any time, make application for a reinspection for the purpose of reinstatement of the permit or certification. Following receipt of a written request, including a statement signed by the applicant that in his or her opinion the conditions causing suspension of the permit have been corrected, the Department shall make a reinspection. If the applicant is complying with the requirements of this Regulation, the permit shall be reinstated. Summaries of the findings of reinspection shall be provided to the owner or manager of the facility at the conclusion of the inspection.

(d) Revocation of Permits or Certifications - Serious or repeated violations of any of the requirements of this Regulation, failure to cooperate, or interference with Department personnel in the performance of their duties shall be cause for a permit or certificate to be revoked. Prior to such action, the Department shall issue notice, in writing, stating the reasons for which the permit or certificate is being revoked. This notice shall also advise that the revocation determination shall be final unless a request for a hearing is filed with the Department within fifteen (15) business days of receipt of the notice. The request for a hearing shall be processed in accordance with the Administrative Procedures Act.

(e) Serving of Notices. A notice outlining the Department's revocation of a permit or certificate is properly served when it is delivered to the permit holder or when it is sent by registered or certified mail, return receipt requested, to the last known address of the permit holder. A copy of any such notice shall be filed in the records of the Department.

2. Inspections.

(a) General. The Department shall inspect each shellfish facility periodically and shall make as many additional inspections and reinspections as are necessary for the effective enforcement of this Regulation.

(b) Access to Processing Facilities, Distributors, Shippers, Reshippers and Vehicles -Authorized representatives of the Department, after proper identification, shall be permitted to enter at any reasonable time, any facility, establishment, or vehicle used to harvest, store or transport shellfish for the purpose of making inspections to determine compliance with this Regulation. The Department's designated representatives shall be permitted to examine the records of a shellfish facility or establishment to obtain information pertaining to shellstock harvested and relayed; shellfish purchased, received, processed, sold, distributed, or shipped; and personnel employed.

I. CERTIFIED SHIPPER FACILITIES.**1. General Sanitation and Controls For Certified Shippers**

(a) HACCP Requirement - Certified Shippers shall comply with all applicable sections of 21CFR110 and 21CFR123.

(b) Facility Location, Grounds, and Arrangement. Shellfish facilities shall be located such that they are not normally subjected to flooding and they must have adequate provisions for drainage. All parts of the shellfish facility and its premises shall be kept clean and free of litter and rubbish. Cleaning operations shall be conducted in such a manner as to prevent contamination of shellfish.

(c) Shellfish Dry Storage.

(1) Certified Shipper facilities shall have non-mobile mechanically refrigerated storage rooms capable of maintaining all unfrozen shellfish at a temperature between thirty-four and forty-five degrees Fahrenheit (one and seven degrees centigrade).

(2) Floors of storage rooms shall be constructed of an impervious material free from cracks, holes, ruts, or other uneven surfaces, and shall be sloped to assure complete and rapid drainage.

(3) Unfrozen shellfish in dry storage shall be maintained at a temperature between thirty-four and forty-five degrees fahrenheit (one and seven degrees centigrade) at all times.

(4) Storage areas shall be protected from flooding.

(5) Food contact areas shall be of impervious, nontoxic material which will not deteriorate under repeated washings.

(6) Storage areas shall not contain materials or equipment unrelated to storage of food products.

(7) Bins, hoppers, sacks, barrels, or other containers shall fully protect stored shellfish from contamination.

(8) Unauthorized persons shall not be present in certified shipper facilities during periods when in operation.

(9) Shellfish shall be stored on clean, elevated, impervious, perforated platforms of a height adequate to prevent contact with water from the floor area.

(10) Frozen shellfish shall be maintained at or below a temperature of zero degrees Fahrenheit (minus eighteen degrees centigrade) at all times.

(d) Water. Supply shall be adequate, of a safe and sanitary quality, and from a source constructed, protected, and operated in accordance with specifications approved by the Department. Water under pressure and at the required temperatures shall be provided in all areas where shellstock or shellfish are processed or where equipment, utensils, or containers are washed.

(e) Plumbing. Plumbing shall be sized, installed, and maintained in compliance with applicable State Regulations and local plumbing ordinances. Drainpipes or wastepipes shall not be located over food, shellfish processing areas, storage areas or areas where containers or utensils are stored or washed.

(f) Restroom Facilities. Each Certified Shipper shall provide employees with properly installed and conveniently located toilet facilities in numbers as required in Section 1910.141, South Carolina Occupational Safety and Health Standards for General Industry, South Carolina Department of Labor. The doors of all restrooms shall be self-closing. Toilet tissue shall be provided. Easily cleanable receptacles with covers shall be provided.

(g) Hand-Washing Facilities. Each Certified Shipper facility shall have an adequate number of conveniently located hand-washing facilities for its employees. This shall include a lavatory or lavatories equipped with hot and cold or tempered running water, hand-cleaning soap or detergent and approved sanitary towels or other approved hand-drying devices. Such facilities shall be kept clean and in good repair. Signs shall be posted in toilet rooms and near lavatories directing all employees to wash their hands before returning to work.

(h) Sewage. Sewage, including liquid waste must be disposed of in a manner approved by the Department.

(i) Garbage and Refuse.

(1) Refuse shall be kept in leakproof, non-absorbent containers which shall be kept covered with tight-fitting lids when filled or stored, or not in continuous use; provided that such containers need not be covered when stored in a special vermin-proofed room or enclosure, or in a waste refrigerator.

(2) Refuse shall be disposed of with sufficient frequency and in such a manner to prevent contamination of shellfish and surrounding processing areas.

(j) Vector Control. Certified Shipper facilities shall be constructed to exclude and control insects, rodents, vermin, and other animals. Outside doors shall be self-closing, tight fitting, and outward opening. Doors between shucking and packing rooms shall be self-closing, and open into the shucking room only.

(k) Ice. When used for processing or storage of shellfish shall be produced from a Department approved water source and shall be stored and handled under conditions which prevent contamination.

(l) Product Recall. All Certified Shippers shall:

(1) adopt and maintain on the premises procedures for conducting recalls of shellfish suspected of being adulterated;

(2) immediately notify the Department of all information including, but not limited to, product identity, deficiency, and extent of distribution regarding shellfish suspected of being adulterated;

(3) immediately institute shellfish recall procedures for shellfish suspected of being adulterated;

(4) fully cooperate with all Departmental investigations.

2. Personnel/Supervision. The certificate holder shall supervise all activities associated with the handling of shellfish or he shall clearly designate a competent individual to be accountable for compliance with this Regulation. Designation of this individual does not relieve said certificate holder of responsibility for compliance.

3. Construction and Maintenance of Physical Facilities.

(a) Floors. The floor surfaces in all rooms, and areas in which shellfish are stored or processed, or where utensils are washed, walk-in refrigerators, dressing or locker rooms, restrooms, and all other areas shall be constructed to be easily cleanable. Floors shall be kept clean and in good repair. Floor drains shall be provided in rooms where floors are subjected to flooding-type cleaning or where normal operations release or discharge water or other liquid waste onto the floor.

(b) Walls and Ceilings. Walls and ceilings of all rooms shall be clean, smooth, washable, in good repair and of light color.

(c) Lighting.

(1) Safe and adequate lighting shall be provided in hand-washing areas, dressing and locker rooms, restrooms, and in all areas where shellfish are processed or where equipment and utensils are cleaned or in areas where containers and other packaging materials are stored.

(2) Shielding to protect against broken glass falling onto exposed shellfish shall be provided for all lighting fixtures located over or within shellfish storage or processing areas.

(d) Heating and Ventilation. Each room and all other areas in the shellfish facility shall be well ventilated when necessary. Heating or ventilation hoods and other devices when used shall not create conditions that will contaminate shellfish. Heating and ventilation systems shall comply with applicable Federal, State and local requirements.

(e) Locker Area. Adequate facilities shall be provided for the orderly storage of employee clothing and personal belongings.

(f) General Maintenance and Cleanliness. Physical facilities shall be kept in good repair and cleaned as necessary to maintain sanitary conditions. Cleaning operations shall not cause contamination of food and food-contact surfaces.

J. SHUCKER-PACKERS.**1. Shucking Area and Equipment Requirements.****(a) Shucking and Packing Area.**

(1) Shucking and packing operations shall be conducted in separate areas. A delivery window shall be installed in the partition between the shucking and packing rooms through which shucked meat to be packaged will be passed to protect against contamination. Shucking and packing may be conducted in the same room only when shuckers are shucking directly into containers.

(2) Shuckers may not go into or through the packing room for any purpose, except when they operate in a dual shucking-packing capacity. A person operating in a dual capacity must change to clean clothing and thoroughly wash his hands and exposed portions of his arms between shucking and packing operations.

(b) Shucking Benches and Tables.

(1) Shucking benches shall be constructed of impervious non-corrosive material, smooth and free of cracks and crevices, and sloped to drain. Shucking blocks shall be of smooth, solid one piece construction and easily cleanable. Footstools shall be constructed of impervious non-corrosive material. Covers shall be provided for shell-chutes to exclude insects and rodents.

(2) There shall be no storage or accumulation of articles over, on, around, or underneath the shucking benches or tables.

(c) Utensils and Equipment.

(1) Equipment and utensils such as pails, buckets, colanders, knives, or similar items contacting shellfish and other food-contact surfaces shall be made of smooth, nontoxic, non-corrosive, non-absorbent materials and shall be cleanable.

(2) Equipment shall be installed and maintained to facilitate cleaning thereof.

(d) Cleaning and Sanitizing Equipment and Utensils -Utensils, equipment, and food-contact surfaces in a shucking-packing facility shall be thoroughly cleaned and, where necessary, sanitized prior to use. Cleaning and sanitizing shall be at such intervals as necessary to prevent contamination. Only chemical sanitizing agents at effective concentrations as specified in 21 CFR 178.101(9) shall be used.

(e) Equipment and Utensil Handling and Storage.

(1) Cleaned and sanitized equipment and utensils shall be protected from contamination at all times.

(2) Disposable articles or utensils such as paper cups and paper towels shall be handled and dispensed in a manner which prevents contamination of shellfish and food contact surfaces.

(3) Single-service containers shall be used only once. Exceptions may be made for containers capable of being recleaned for reuse if approved by the Department.

(4) Cleaned and sanitized utensils and equipment shall be properly stored to prevent contamination.

(f) General Maintenance.

(1) Shucking-packing facilities shall be well maintained and cleaned daily to maintain sanitary conditions. Cleaning operations shall not cause contamination of shellfish and food-contact surfaces. Cleaning and sanitizing operations shall be safe, effective, and in compliance with 21 CFR 178.101 (9).

(2) Only authorized equipment and persons shall be permitted in the shellfish processing area. Animals shall not be allowed in shellfish processing areas.

(g) Employee Garments. Employees shucking or handling shellfish meat shall wear clean aprons or coats and effective hair restraints. Sanitized rubber gloves or equivalent shall be worn when handling shellfish meats, or the hands shall be washed and disinfected immediately before such handling. Finger cots,

gloves, or shields, if worn by shuckers, shall be sanitized as often as necessary to prevent contamination.

2. Shucking-Packing Operations.

(a) Shellfish Source. Only clean, live shellstock maintained at an appropriate temperature and received from an approved source shall be shucked. Shellstock not properly identified as stated in C.2(a) shall not be shucked.

(b) Shucking Procedures.

(1) Shellstock shall be shucked in a manner that will not contaminate the shucked meat.

(2) Shucked meats shall be delivered for packaging under such conditions that will prevent contamination and spoilage. There shall be no commingling of shucked meats from shellstock obtained from different sources.

(c) Shell and Waste Disposal. Shells and meat waste shall be promptly removed and disposed of in a manner that will not contaminate the shucked product or the shellfish processing facility and grounds, nor cause a nuisance or health hazard.

(d) Packing and Packaging.

(1) Shellfish meats shall be drained and cleaned as necessary and packaged or repackaged without being exposed to contamination or spoilage.

(2) Materials used in the packing or repacking of shucked shellfish shall be in compliance with the Federal Food, Drug, and Cosmetic Act and State and local regulations.

(e) Refrigeration.

(1) Shucked shellfish shall be cooled to an internal temperature of forty-five degrees fahrenheit (seven degrees centigrade) or less within two hours after delivery to the packing room. Shucked shellfish in storage shall be maintained between thirty-four and forty-five degrees fahrenheit (one and seven degrees centigrade) at all times. Refrigeration units shall be equipped as follows:

(a) An automatic temperature-regulating control;

(b) An indicating thermometer installed to indicate accurately the temperature within the storage compartments.

(2) Packaged shellfish to be frozen shall be stacked to insure rapid freezing, and shall be frozen at an ambient air temperature of zero degrees fahrenheit (minus eighteen degrees centigrade) or less, with packages frozen solid within twelve hours after the start of freezing. Frozen shellfish shall be handled in such a manner as to remain frozen solid and shall be held at zero degrees fahrenheit (minus eighteen degrees centigrade) or less.

(f) Ice. Ice used for processing or storage of shellfish shall be produced from a Department approved water source and shall be stored and handled under conditions which prevent contamination.

(g) Records. Complete, accurate, and legible daily records shall be maintained on the facility premises in a bound ledger book or computer file, in a format approved by the Department. Records shall be readily available when requested for inspection for a period of one year for shellstock or shucked shellfish, and for a period of two years for frozen shucked shellfish and shall contain the following information:

(1) Source of the shellfish;

(2) Quantity obtained;

(3) Date obtained;

(4) Area from which shellfish were harvested;

(5) Date Harvested;

(6) Date shucked and packed;

(7) Names of the persons to whom the shellfish were sold or distributed.

(h) Shipping Documents files are to be completed daily, kept with facility records, and readily available to the Department when requested.

3. Heat Shock Processing of Shellfish for Shucking.

(a) General. Scheduled processes for heat shock shall be established by the Department or by qualified persons, or in cooperation with qualified persons having adequate facilities for making such determinations. Alternative scheduled processes for heat shock shall be approved by the Department. The type, range, and combination of variations encountered in commercial heat shock operations shall be adequately provided for in establishing the scheduled process. Critical factors which may affect the scheduled process including species and size of the shellfish, time and temperature, and type of process shall be determined on the basis of a study of the effectiveness of the process. The scheduled process shall be such that the shellfish are not killed by the heat shock, the physical and organic properties of the shucked shellfish are not significantly changed, and the completed process does not cause additional microbiological deterioration of the shucked shellfish. Complete records covering all aspects of the scheduled process study and specifications shall be maintained by the person making the determination. Process schedules shall be posted in the facility .

(b) Tank Design Construction and Water Requirements.

(1) The heat shock tank shall be constructed of smooth, non-corrosive material, designed to drain quickly and completely, and designed to facilitate cleaning.

(2) Heat shock tanks shall be equipped with booster heaters that are thermostatically controlled.

(c) Shellstock Washing. Shellstock subjected to the heat shock process shall be thoroughly washed with flowing potable water immediately prior to the heat shock operation.

(d) Water Temperature. During the heat shock process the water shall be maintained at not less than one hundred and forty-five degrees fahrenheit (sixty-three degrees centigrade) nor more than one hundred and fifty degrees fahrenheit (sixty-five degrees centigrade). An accurate thermometer shall be used to determine the temperature during the heat shock process.

(e) Time Requirements. Shellstock subjected to the heat shock process shall be immersed in the shock water in accordance with the criteria specified in J.3(a). An accurate timing device shall be available and used to determine the immersion time.

(f) Water Requirements. Each tank shall contain at least eight gallons of water for each one half bushel of shellstock being treated.

(g) Cooling. Immediately after heat shocking, shocked shellstock shall be cooled-down with potable water. Heat shocked shellstock shall be handled in a manner to prevent adulteration of the product. Shucked shellfish which have been subjected to the heat shock process shall be cooled to an internal temperature of forty-five degrees fahrenheit (seven degrees centigrade) or below within two hours after this process and shall be placed in storage at thirty-four to forty-five degrees fahrenheit (one to seven degrees centigrade).

(h) Cleaning. The heat shock tank shall be completely emptied of all water, mud, and detritus, and thoroughly cleaned and rinsed with flowing potable water every three hours. Water, mud, detritus, and other by-products shall be disposed of in a manner approved by the Department.

(i) Alternatives to Heat Shock Process. This Section shall not be construed to prohibit any other process which has been found equally effective and has been approved by the Department.

K. REPACKERS.

1. If shucked shellfish are repacked, the operation shall be conducted strictly in accordance with the requirements stipulated for shucking and packing facilities in Section J., except those relating specifically to shucking.

2. Shucked shellfish for repacking shall be obtained only from certified shippers. Shucked shellfish not properly labeled as defined in C.2(b) shall not be repacked.

3. The shucked shellfish to be repacked shall be received at the repacking facility in approved shipping containers at a temperature between thirty-four and forty-five degrees fahrenheit (one and seven degrees centigrade).

4. Shellfish shall not be repacked more than one time.

5. The temperature of the shellfish shall not exceed forty-five degrees fahrenheit (seven degrees centigrade) during the repacking process.

6. Complete, accurate, and legible daily records shall be maintained on the facility premises in a bound ledger book or computer file, in a format approved by the Department. Records shall be readily available when requested for inspection for a period of one year for shellstock or shucked shellfish, and for a period of two years for frozen shucked shellfish and shall contain the following information;

(a) The date the shellfish were obtained;

(b) The quantity of shellfish;

(c) Type of shellfish;

(d) For shellstock, a descriptive name or number of the specific harvest area, the original shipper's certification number including the State abbreviation, and the certification number of the shipper from whom the shellfish were obtained. For shucked shellfish, the certification number of the shipper from whom the shellfish were obtained as well as the certification number of the original Shucker-Packer or Repacker;

(e) The date of repacking;

(f) Name and address of each person to whom shellfish are sold, given, or otherwise transferred, along with the date of each transaction.

7. Shipping Documents files are to be completed daily, kept with facility records, and readily available to the Department when requested.

8. Frozen shellfish which have thawed shall not be repacked or repackaged.

9. When ice is used as a means of cooling, it shall conform to J.2(f).

10. Refrigeration of all repacked shucked shellfish shall conform to J.2(e).

11. Repacking and repackaging shall conform to J.2(d).

12. Each container of repacked shucked shellfish shall be labeled and identified to meet the requirements of C.2(b).

13. Shucked shellfish from different lots shall not be commingled during repacking.

L. SHELLSTOCK SHIPPERS.

1. Source. Shellstock shall originate from an approved source. Each lot of shellstock shall be identified in accordance with C.2(a).

2. Containers. Shellstock shall be packed and shipped in clean container.

3. Records. Complete, accurate, and legible daily records shall be maintained on the facility premises in a bound ledger book or computer file, in a format approved by the Department. Records shall be readily available when requested for inspection for a period of one year for shellstock or shucked shellfish, and for a period of two years for frozen shucked shellfish and shall contain the following information;

(a) The quantity of shellfish;

(b) Type of shellfish;

(c) For shellstock, a descriptive name or number of the specific harvest area, the original shipper's certification number including the State abbreviation, and the certification number of the shipper from whom the shellfish were obtained. For shucked shellfish, the certification number of the shipper from whom the shellfish were obtained as well as the certification number of the original Shucker-Packer or Repacker;

(d) For shellstock, the date the shellstock were obtained as well as the date harvested. For shucked shellfish, the date the shellfish were obtained as well as the applicable shucked date or sell by date;

(e) Name and address of each person to whom shellfish are sold, given or otherwise transferred along with the date of each transaction;

(f) Shipping Documents files are to be completed daily, kept with facility records, and readily available to the Department when requested.

M. RESHIPERS

1. Shellfish shall be obtained only from a certified shipper. Shellfish that are not properly identified or are not properly labeled as defined in C.2(a)(2)(a) and C.2(b) shall not be received.

2. Refrigeration shall be maintained for each type of shellfish reshipped as outlined in I.1(c) and J.2(e).

3. Records

(a) Complete, accurate, and legible daily records shall be maintained on the facility premises in a bound ledger book or computer file, in a format approved by the Department. Records shall be readily available when requested for inspection for a period of one year for shellstock or shucked shellfish, and for a period of two years for frozen shucked shellfish and shall contain the following information;

(1) The quantity of shellfish;

(2) Type of shellfish;

(3) For shellstock, the original shipper's certification number including the State abbreviation, and the certification number of the shipper from whom the shellfish were obtained. For shucked shellfish, the certification number of the shipper from whom the shellfish were obtained as well as the certification number of the original Shucker-Packer or Repacker;

(4) For shellstock, the date the shellstock were obtained as well as the date harvested, for shucked shellfish, the date the shellfish were obtained as well as the applicable shucked date or sell by date;

(5) For shellstock, the harvest area;

(6) Name and address of each person to whom shellfish are sold, given or otherwise transferred along with the date of each transaction.

(b) Shipping Documents files are to be completed daily, kept with facility records, and readily available to the Department when requested.

N. DEPURATION.**1. General Administration.**

(a) Permitting Requirement. A Permit for facility construction shall be obtained from the Department prior to constructing any depuration facility. A scheduled depuration process (SDP) which addresses all aspects of the proposed operation shall be provided in conjunction with the Depuration Facility Construction Permit application.

(b) Plan Review. Plans for construction or remodeling of depuration facilities which evidence compliance with all applicable portions of section N.2 shall be reviewed and approved by the Department prior to construction.

(c) Supervision. Depuration activities shall be supervised by the Department to prevent polluted shellfish from being diverted into the marketplace prior to purification. Shellfish purified by depuration shall remain at the facility and shall not be utilized in any way until approved by the Department.

(d) Responsibility. The depuration certificate and/or permit holder shall be responsible for all depuration activities, from harvest through delivery of depurated shellfish, as appropriate. Violation of any item in this Regulation shall constitute grounds for revocation of the certificate/permit and penalties as specified in Section H. and Section P.

(e) Inspections. An inspection of each depuration facility shall be conducted routinely by the Department to insure compliance with this Regulation.

(f) Process Verification. A scheduled depuration process (SDP) shall be established and approved by the Department prior to certification of each depuration facility. The SDP shall address the type, range and combinations of variables encountered in depuration. Critical control points shall be specified in the SDP.

2. Facility Design and Equipment.

(a) The facility shall be designed to physically separate undeputed shellstock from depurated shellstock and shall be approved by the Department.

(b) Tanks, containers, and water lines shall be designed and constructed as follows.

(1) Processing tanks, shellfish containers, valves, and water lines shall be of nontoxic, corrosion resistant material which are easily cleanable.

(2) Tanks shall be constructed to allow self-draining and easy accessibility for cleaning or inspection.

(3) Tanks shall be designed and constructed to allow uniform circulation of water.

(4) Shellfish containers shall be of mesh-type construction to allow water flow to all shellfish in the containers.

3. Depuration Facility Operations.

(a) Harvesting.

(1) Harvesting activities shall conform to the applicable portions of Sections C and G of this Regulation.

(2) Shellfish destined for depuration facilities shall be protected as necessary to prevent contamination and undue physiological stress.

(b) Source. Shellfish intended for depuration shall be harvested from growing areas meeting the water quality criteria for Approved, Conditionally Approved, Restricted, or Conditionally Restricted areas.

(c) Pre-Depuration Identification. Shellfish destined for depuration facilities shall be identified in accordance with Section C.

(d) Pre-Depuration Storage. Shellfish stored prior to depuration shall be maintained at the approximate temperature of the harvest waters.

(e) Washing and Culling. Shellfish intended for depuration shall be washed and culled; both prior to and following the depuration process.

(f) Depurated Shellfish Identification.

(1) Depurated shellfish shall be identified in accordance with Section C., and the tag shall be stamped with the word “depurated” or DEP.

(2) Labeling shall be conducted immediately upon containerizing the depurated shellfish.

(g) Containers. Depurated shellfish shall be packed in clean containers.

(h) Transportation of Depurated Shellfish. Depurated shellfish shall be transported in accordance with Section C.

(i) Records.

(1) Records of shellfish harvested, depurated, and released for market shall be maintained on the facility premises and be readily available for one year. The records shall include the number of containers (bags, sacks, boxes, etc.), and shall identify the quantity by volume in the container. The dates shellfish were placed in and released from depuration shall be recorded. Records shall also include the origin and destination of each depurated shellfish lot, by code and date. Shellfish released for market shall be tagged in accordance with all applicable sections of this Regulation.

(2) A time/dated log sheet shall be kept at each depuration facility. This log sheet shall include, but not necessarily be limited to the following:

(i) Time of entry of shellfish into depuration tanks and time of removal of shellfish from depuration tanks;

(ii) Temperature of depuration tank water (twice daily);

(iii) Salinity of depuration tank water (daily);

(iv) Beginning and ending times for ultraviolet disinfection of each depurated shellfish lot;

(v) Water flow [expressed in gallons per minute (gpm);]

(vi) Dissolved oxygen (daily);

(vii) The date and time each depuration tank is drained, cleaned, and refilled.

O. SHELLFISH AQUACULTURE.

1. General.

(a) For purposes of this Regulation, aquaculture encompasses the following:

- (1) Open water and/or Land based operations;
- (2) Monoculture (molluscan shellfish) or Polyculture (molluscan shellfish combined with non-molluscan organisms) production.

(b) Any person operating a land based aquaculture facility which grows or produces molluscan shellfish for sale shall obtain the following from the Department prior to commencing operations or harvesting shellfish for human consumption:

- (1) An Aquaculture Facility Construction Permit based upon criteria described in the facility's approved operational plan as required by Section O.4(a); and
- (2) An Aquaculture Operating Permit based upon successfully meeting the requirements of all applicable portions of this Regulation; and
- (3) Certification as a processor, unless the permitted aquaculturist provides the Department with prior notice that harvested shellfish are to be delivered to a Shucker-Packer(SP), Repacker(RP), Shellstock Shipper(SS), or Depuration Processor(DP) within the State.

(c) Any person operating an open water aquaculture facility which grows or produces molluscan shellfish for sale shall obtain the following from the Department prior to commencing operations or harvesting shellfish for human consumption:

- (1) An Aquaculture Operating Permit based upon successfully meeting the requirements of all applicable portions of this Regulation; and
- (2) Certification as a processor, unless the permitted aquaculturist provides the Department with prior notice that harvested shellfish are to be delivered to a Shucker-Packer(SP), Repacker(RP), Shellstock Shipper (SS), or Depuration Processor (DP) within the State.

(d) Shellfish aquaculture shall be practiced only in strict compliance with the specific provisions of the Aquaculture Permit;

(e) Applications for Aquaculture Permits must contain a written operational plan detailing the scope and extent of the operation.

(f) Water quality at any site used for aquaculture shall meet the criteria for an approved, conditionally approved, or restricted area classification.

(g) Shellfish cultured in any land based system meeting the criteria for an approved area classification throughout the culture period may be immediately marketed.

(h) Any shellfish raised in aquaculture shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in one of the following:

(1) A conditionally approved area classification in a “closed” status;

or

(2) A restricted area classification.

(i) Only drugs approved by the USFDA shall be used for shellfish treatment.

(j) Complete and accurate records shall be maintained for at least two years by the aquaculturist and shall include the:

(1) Source of shellfish, including seed;

(2) Dates of transplanting and harvest; and

(3) Water source, its treatment method, if necessary, and its quality inland based systems.

(k) Harvesting, processing, storage, and transportation of shellfish shall comply with all other applicable requirements of this Regulation.

2. Seed-Aquaculture Permit holders shall provide the Department with documentation concerning the source of seed shellstock.

3. Open water Aquaculture shall comply with all applicable requirements of C.1 and C.2 of this Regulation.

4. Land Based Shellfish Aquaculture permit applicants shall provide the following to the Department:

(a) A written operational plan which shall include:

(1) A description of the design and activities of the aquaculture facility;

(2) The specific site and boundaries in which shellfish culture activities will be conducted;

(3) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats utilized in the aquaculture operation;

(4) The species of shellfish to be cultured and harvested;

(5) If appropriate, the source and species of other organisms to be cultured in any polyculture systems;

(6) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;

(7) A program of sanitation, maintenance, and supervision to prevent contamination of the final shellfish products;

(8) A description of the water source, including the details of any water treatment process or method, if necessary;

(9) A program to maintain water quality which includes collection of water samples for microbial analysis, temperature and salinity monitoring, and analytical methods used. The bacterial indicator monitored shall be the same as used for monitoring growing areas;

(10) Maintenance of the required records; and

(11) How shellstock will be harvested, processed if applicable, and sold.

(b) Water Systems.

(1) Water disinfection will not be required if shellfish are held at all times in continuous flow through systems which utilize water from an approved growing area, or from a conditionally approved area in the approved status.

(2) Closed or recirculating systems shall:

(a) Not contaminate shellfish with residues that are not Generally Recognized As Safe (GRAS) [see 21 Code of Federal Register (CFR);]

(b) Come only from waters classified “approved” or “restricted”;

(c) Be maintained, at a minimum, at the bacteriological quality of the restricted classification; and

(3) If the water in the closed or recirculating system is from water classified as conditionally approved, the operational plan shall include a sampling schedule and shellfish shall not be harvested until:

(a) a total of three water samples have been collected from the system a minimum of three days apart over a 14 day period; and

(b) fecal coliform levels in each sample are not greater than 14 MPN per 100 ml.

(c) Water Quality.

(1) Shellstock held at all times in waters meeting the criteria for an approved area may be used for direct marketing;

(2) If the water in a closed or recirculating system is from a source classified as conditionally approved and in the open status, shellstock may be marketed directly if the water quality meets a fecal coliform level of less than 14 MPN per 100 ml. in each sample collected in the 14 days prior to harvest.

(3) Shellstock in a closed or recirculating system which does not meet the water quality requirements of items O.4(c)(1) or O.4(c)(2) shall be relayed or depurated prior to direct marketing.

5. Aquaculture Permit Applicants engaging in Polyculture activities shall include in its operational plan requirements to:

(a) Provide information concerning all sources and species of all organisms to be cultivated, cultured, and harvested;

(b) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and

(c) Subject all harvested shellstock to relaying or depuration:

6. Activities related solely to the production of seed shellstock shall be exempt from this Regulation.

7. Operators of Shellfish Mariculture Areas as permitted by the South Carolina Department of Natural Resources shall provide the Department with a written operational plan which shall include:

(a) A description of activities associated with the operation;

(b) The specific site and boundaries in which shellfish culture activities will be conducted;

(c) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats utilized in the aquaculture operation;

(d) The type of shellfish to be cultured and harvested;

(e) Documentation of the source of seed shellstock.

P. REMEDIES.

1. General. In addition to the provisions herein for administrative suspension or revocation of operating permits, the Department may, at its discretion, bring civil court proceedings to enforce provisions of this Regulation, and may also seek to impose criminal sanctions for violation of this Regulation.

2. Criminal Liability. Violation of any provision of this Regulation shall be punishable in accordance with Section 44-1-150 and Section 44-1-151, Code of Laws of South Carolina, 1976, and any subsequent amendments.